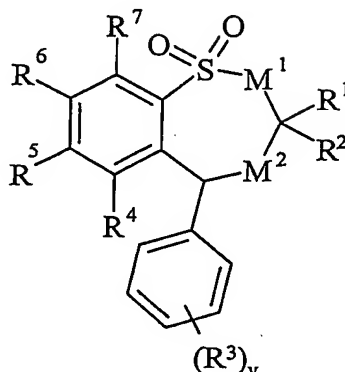


Claims

1. A compound of formula (I):



(I)

wherein

M^1 is $-CH_2-$ or $-NR^{21}-$;

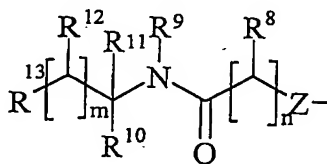
M^2 is $-CR^{22}R^{23}-$ or $-NR^{24}-$; provided that if M^1 is $-NR^{21}-$, M^2 is $-CR^{22}R^{23}-$;

One of R^1 and R^2 are selected from hydrogen, C_{1-6} alkyl or C_{2-6} alkenyl and the other is
10 selected from C_{1-6} alkyl or C_{2-6} alkenyl;

R^3 is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-6} alkoxy, C_{1-6} alkanoyl, C_{1-6} alkanoyloxy, $N-(C_{1-6}alkyl)amino$, $N,N-(C_{1-6}alkyl)_2amino$, $C_{1-6}alkanoylamino$, $N-(C_{1-6}alkyl)carbamoyl$, $N,N-(C_{1-6}alkyl)_2carbamoyl$, $C_{1-6}alkylS(O)_a$ wherein a is 0 to 2, $C_{1-6}alkoxycarbonyl$,
15 $N-(C_{1-6}alkyl)sulphamoyl$ and $N,N-(C_{1-6}alkyl)_2sulphamoyl$;

v is 0-5;

one of R^5 and R^6 is a group of formula (IA):



(IA)

20 R^4 and R^7 and the other of R^5 and R^6 are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C_{1-4} alkyl, C_{2-4} alkenyl, C_{2-4} alkynyl, C_{1-4} alkoxy, C_{1-4} alkanoyl, C_{1-4} alkanoyloxy, $N-(C_{1-4}alkyl)amino$, $N,N-(C_{1-4}alkyl)_2amino$, $C_{1-4}alkanoylamino$, $N-(C_{1-4}alkyl)carbamoyl$,

N,N-(C₁₋₄alkyl)₂carbamoyl, C₁₋₄alkylS(O)_a wherein a is 0 to 2, C₁₋₄alkoxycarbonyl, *N*-(C₁₋₄alkyl)sulphamoyl and *N,N*-(C₁₋₄alkyl)₂sulphamoyl; wherein R⁴ and R⁷ and the other of R⁵ and R⁶ may be optionally substituted on carbon by one or more R²⁵;

Z is -O-, -N(R^a)-, -S(O)_b- or -CH(R^a)-; wherein R^a is hydrogen or C₁₋₆alkyl and b is 0-5 2;

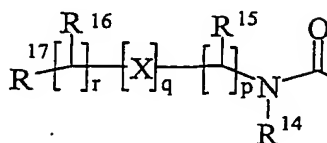
R⁸ is hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; wherein R⁸ may be optionally substituted on carbon by one or more substituents selected from R²⁶; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R²⁷;

10 R⁹ is hydrogen or C₁₋₄alkyl;

R¹⁰ and R¹¹ are independently selected from hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; or R¹⁰ and R¹¹ together form C₂₋₆alkylene; wherein R¹⁰ and R¹¹ or R¹⁰ and R¹¹ together may be independently optionally substituted on carbon by one or more substituents selected from R²⁸; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen
15 may be optionally substituted by one or more R²⁹;

R¹² is hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; wherein R¹² may be optionally substituted on carbon by one or more substituents selected from R³⁰; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen may be optionally substituted by one or more R³¹;

20 R¹³ is hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C₁₋₁₀alkyl, C₂₋₁₀alkenyl, C₂₋₁₀alkynyl, C₁₋₁₀alkoxy, C₁₋₁₀alkoxycarbonyl, C₁₋₁₀alkanoyl, C₁₋₁₀alkanoyloxy, *N*-(C₁₋₁₀alkyl)amino, *N,N*-(C₁₋₁₀alkyl)₂amino, *N,N,N*-(C₁₋₁₀alkyl)₃ammonio, C₁₋₁₀alkanoylamino, *N*-(C₁₋₁₀alkyl)carbamoyl, *N,N*-(C₁₋₁₀alkyl)₂carbamoyl, C₁₋₁₀alkylS(O)_a wherein a is 0 to 2,
25 *N*-(C₁₋₁₀alkyl)sulphamoyl, *N,N*-(C₁₋₁₀alkyl)₂sulphamoyl, *N*-(C₁₋₁₀alkyl)sulphamoylamino, *N,N*-(C₁₋₁₀alkyl)₂sulphamoylamino, C₁₋₁₀alkoxycarbonylamino, carbocyclyl, carbocyclylC₁₋₁₀alkyl, heterocyclic group, heterocyclylC₁₋₁₀alkyl, carbocyclyl-(C₁₋₁₀alkylene)_e-R³²-(C₁₋₁₀alkylene)_f or heterocyclyl-(C₁₋₁₀alkylene)_g-R³³-(C₁₋₁₀alkylene)_h; wherein R¹³ may be optionally substituted
30 on carbon by one or more substituents selected from R³⁶; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R³⁷; or R¹³ is a group of formula (IB):



(IB)

wherein:

X is $-N(R^{38})-$, $-N(R^{38})C(O)-$, $-O-$, and $-S(O)_a-$; wherein a is 0-2 and R^{38} is hydrogen or

5 C_{1-4} alkyl;

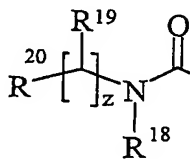
R^{14} is hydrogen or C_{1-4} alkyl;

R^{15} and R^{16} are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-6} alkoxy, C_{1-6} alkanoyl, C_{1-6} alkanoyloxy, $N-(C_{1-6}$ alkyl)amino, $N,N-(C_{1-6}$ alkyl)₂amino,

10 C_{1-6} alkanoylamino, $N-(C_{1-6}$ alkyl)carbamoyl, $N,N-(C_{1-6}$ alkyl)₂carbamoyl, C_{1-6} alkylS(O)_a wherein a is 0 to 2, C_{1-6} alkoxycarbonyl, $N-(C_{1-6}$ alkyl)sulphamoyl, $N,N-(C_{1-6}$ alkyl)₂sulphamoyl, carbocyclyl or heterocyclic group; wherein R^{15} and R^{16} may be independently optionally substituted on carbon by one or more substituents selected from R^{41} ; and wherein if said heterocyclyl contains an $-NH-$ group, that nitrogen may be optionally substituted by a group
15 selected from R^{42} ;

R^{17} is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C_{1-10} alkyl, C_{2-10} alkenyl, C_{2-10} alkynyl, C_{1-10} alkoxy, C_{1-10} alkanoyl, C_{1-10} alkanoyloxy, $N-(C_{1-10}$ alkyl)amino, $N,N-(C_{1-10}$ alkyl)₂amino, C_{1-10} alkanoylamino, $N-(C_{1-10}$ alkyl)carbamoyl, C_{1-10} alkoxycarbonyl,

20 $N,N-(C_{1-10}$ alkyl)₂carbamoyl, C_{1-10} alkylS(O)_a wherein a is 0 to 2, $N-(C_{1-10}$ alkyl)sulphamoyl, $N,N-(C_{1-10}$ alkyl)₂sulphamoyl, $N-(C_{1-10}$ alkyl)sulphamoylamino, $N,N-(C_{1-10}$ alkyl)₂sulphamoylamino, carbocyclyl, carbocyclyl C_{1-10} alkyl, heterocyclic group, heterocyclyl C_{1-10} alkyl, carbocyclyl- $(C_{1-10}$ alkylene)_e- R^{43} - $(C_{1-10}$ alkylene)_f or heterocyclyl- $(C_{1-10}$ alkylene)_g- R^{44} - $(C_{1-10}$ alkylene)_h; wherein R^{17} may be optionally substituted
25 on carbon by one or more substituents selected from R^{47} ; and wherein if said heterocyclyl contains an $-NH-$ group, that nitrogen may be optionally substituted by a group selected from R^{48} ; or R^{17} is a group of formula (IC):



(IC)

wherein:

R^{18} is selected from hydrogen or C_{1-4} alkyl;

- 5 R^{19} is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-6} alkoxy, C_{1-6} alkanoyl, C_{1-6} alkanoyloxy, N -(C_{1-6} alkyl)amino, N,N -(C_{1-6} alkyl) $_2$ amino, C_{1-6} alkanoylamino, N -(C_{1-6} alkyl)carbamoyl, N,N -(C_{1-6} alkyl) $_2$ carbamoyl, C_{1-6} alkylS(O) $_a$ wherein a is 0 to 2, C_{1-6} alkoxycarbonyl, N -(C_{1-6} alkyl)sulphamoyl, N,N -(C_{1-6} alkyl) $_2$ sulphamoyl, carbocyclyl or
- 10 heterocyclic group; where R^{19} may be independently optionally substituted on carbon by one or more substituents selected from R^{51} ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R^{52} ;

- R^{20} is selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C_{1-10} alkyl, C_{2-10} alkenyl, C_{2-10} alkynyl, C_{1-10} alkoxy,
- 15 C_{1-10} alkoxycarbonyl, C_{1-10} alkanoyl, C_{1-10} alkanoyloxy, N -(C_{1-10} alkyl)amino, N,N -(C_{1-10} alkyl) $_2$ amino, N,N,N -(C_{1-10} alkyl) $_3$ ammonio, C_{1-10} alkanoylamino, N -(C_{1-10} alkyl)carbamoyl, N,N -(C_{1-10} alkyl) $_2$ carbamoyl, C_{1-10} alkylS(O) $_a$ wherein a is 0 to 2, N -(C_{1-10} alkyl)sulphamoyl, N,N -(C_{1-10} alkyl) $_2$ sulphamoyl, N -(C_{1-10} alkyl)sulphamoylamino, N,N -(C_{1-10} alkyl) $_2$ sulphamoylamino, C_{1-10} alkoxycarbonylamino, carbocyclyl,
- 20 carbocyclyl C_{1-10} alkyl, heterocyclic group, heterocyclyl C_{1-10} alkyl, carbocyclyl-(C_{1-10} alkylene) $_e$ - R^{53} -(C_{1-10} alkylene) $_f$ or heterocyclyl-(C_{1-10} alkylene) $_g$ - R^{54} -(C_{1-10} alkylene) $_h$; wherein R^{20} may be independently optionally substituted on carbon by one or more R^{57} ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R^{58} ;
- 25 p is 1-3; wherein the values of R^{15} may be the same or different;
- q is 0-1;
- r is 0-3; wherein the values of R^{16} may be the same or different;
- m is 0-2; wherein the values of R^{12} may be the same or different;
- n is 1-2; wherein the values of R^8 may be the same or different;
- 30 z is 0-3; wherein the values of R^{19} may be the same or different;

R^{21} is selected from hydrogen or C_{1-6} alkyl;

R^{22} and R^{23} are independently selected from hydrogen, hydroxy, amino, mercapto, C_{1-6} alkyl, C_{1-6} alkoxy, N -(C_{1-6} alkyl)amino, N,N -(C_{1-6} alkyl)₂amino, C_{1-6} alkylS(O)_a wherein a is 0 to 2;

5 R^{24} is selected from hydrogen, hydroxy, C_{1-6} alkyl, C_{1-4} alkoxy and C_{1-6} alkanoyloxy;

R^{25} is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C_{1-4} alkyl, C_{2-4} alkenyl, C_{2-4} alkynyl, C_{1-4} alkoxy, C_{1-4} alkanoyl, C_{1-4} alkanoyloxy, N -(C_{1-4} alkyl)amino, N,N -(C_{1-4} alkyl)₂amino, C_{1-4} alkanoylamino, N -(C_{1-4} alkyl)carbamoyl, N,N -(C_{1-4} alkyl)₂carbamoyl, C_{1-4} alkylS(O)_a wherein a is 0 to 2, C_{1-4} alkoxycarbonyl,

10 N -(C_{1-4} alkyl)sulphamoyl and N,N -(C_{1-4} alkyl)₂sulphamoyl; wherein R^{25} , may be independently optionally substituted on carbon by one or more R^{67} ;

R^{26} , R^{28} , R^{30} , R^{36} , R^{41} , R^{47} , R^{51} and R^{57} are independently selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C_{1-10} alkyl, C_{2-10} alkenyl, C_{2-10} alkynyl, C_{1-10} alkoxy, C_{1-10} alkanoyl, C_{1-10} alkanoyloxy, C_{1-10} alkoxycarbonyl,

15 N -(C_{1-10} alkyl)amino, N,N -(C_{1-10} alkyl)₂amino, N,N,N -(C_{1-10} alkyl)₃ammonio,

C_{1-10} alkanoylamino, N -(C_{1-10} alkyl)carbamoyl, N,N -(C_{1-10} alkyl)₂carbamoyl, C_{1-10} alkylS(O)_a

wherein a is 0 to 2, N -(C_{1-10} alkyl)sulphamoyl, N,N -(C_{1-10} alkyl)₂sulphamoyl,

N -(C_{1-10} alkyl)sulphamoylamino, N,N -(C_{1-10} alkyl)₂sulphamoylamino,

C_{1-10} alkoxycarbonylamino, carbocyclyl, carbocyclyl C_{1-10} alkyl, heterocyclic group,

20 heterocyclyl C_{1-10} alkyl, carbocyclyl-(C_{1-10} alkylene)_e- R^{59} -(C_{1-10} alkylene)_f or

heterocyclyl-(C_{1-10} alkylene)_g- R^{60} -(C_{1-10} alkylene)_h; wherein R^{26} , R^{28} , R^{30} , R^{36} , R^{41} , R^{47} , R^{51} and R^{57} may be independently optionally substituted on carbon by one or more R^{63} ; and

wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R^{64} ;

25 R^{27} , R^{29} , R^{31} , R^{37} , R^{42} , R^{48} , R^{52} , R^{58} and R^{64} are independently selected from

C_{1-6} alkyl, C_{1-6} alkanoyl, C_{1-6} alkylsulphonyl, sulphamoyl, N -(C_{1-6} alkyl)sulphamoyl,

N,N -(C_{1-6} alkyl)₂sulphamoyl, C_{1-6} alkoxycarbonyl, carbamoyl, N -(C_{1-6} alkyl)carbamoyl,

N,N -(C_{1-6} alkyl)₂carbamoyl, benzyl, phenethyl, benzoyl, phenylsulphonyl and phenyl;

R^{32} , R^{33} , R^{43} , R^{44} , R^{53} , R^{54} , R^{59} and R^{60} are independently selected from -O-, - NR^{65} -,

30 -S(O)_x-, - $NR^{65}C(O)NR^{66}$ -, - $NR^{65}C(S)NR^{66}$ -, -OC(O)N=C-, - $NR^{65}C(O)$ - or - $C(O)NR^{65}$ -;

wherein R^{65} and R^{66} are independently selected from hydrogen or C_{1-6} alkyl, and x is 0-2;

R^{63} and R^{67} are independently selected from halo, hydroxy, cyano, carbamoyl, ureido, amino, nitro, carbamoyl, mercapto, sulphamoyl, trifluoromethyl, trifluoromethoxy, methyl, ethyl, methoxy, ethoxy, vinyl, allyl, ethynyl, methoxycarbonyl, formyl, acetyl, formamido, acetylamino, acetoxy, methylamino, dimethylamino, *N*-methylcarbamoyl,

5 *N,N*-dimethylcarbamoyl, methylthio, methylsulphinyl, mesyl, *N*-methylsulphamoyl and *N,N*-dimethylsulphamoyl; and

e, f, g and h are independently selected from 0-2;

or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

10 2. A compound of formula (I) according to claim 1 wherein M^1 is $-CH_2-$ and M^2 is $-CR^{22}R^{23}-$; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

3. A compound of formula (I) according to claim 1 wherein M^1 is $-CH_2-$ and M^2 is $-NR^{24}-$; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

4. A compound of formula (I) according to claim 1 or 2 wherein R^{22} and R^{23} are independently selected from hydrogen and hydroxy; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

5. A compound of formula (I) according to claim 1 or 3 wherein R^{24} is hydrogen; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

25 6. A compound of formula (I) according to any one of claims 1-5 wherein R^1 and R^2 are C_{1-4} alkyl; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

7. A compound of formula (I) according to any one of claims 1-6 wherein v is 0; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

8. A compound of formula (I) according to any one of claims 1-7 wherein R^4 and R^7 are hydrogen; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof;
- 5 9. A compound of formula (I) according to any one of claims 1-8 wherein the R^5 or R^6 not selected from a group of formula (IA) is hydrogen or methylthio; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
10. A compound of formula (I) according to any one of claims 1-9 wherein one of R^5 and
- 10 R^6 is a group of formula (IA) (as depicted above); wherein:
- Z is -O- or -S(O)_b-; wherein b is 0;
- R^8 is hydrogen;
- R^9 is hydrogen;
- R^{10} and R^{11} are independently selected from hydrogen or carbocyclyl; wherein R^{10} and
- 15 R^{11} may be independently optionally substituted on carbon by one or more substituents selected from R^{28} ;
- R^{13} is a group of formula (IB) (as depicted above);
- R^{14} is hydrogen;
- R^{15} is hydrogen;
- 20 R^{17} is C₁₋₁₀alkyl; wherein R^{17} may be optionally substituted on carbon by one or more substituents selected from R^{47} ; or R^{17} is a group of formula (IC) (as depicted above) wherein:
- R^{18} is selected from hydrogen;
- R^{19} is selected from hydrogen;
- R^{20} is C₁₋₁₀alkyl; wherein R^{20} may be independently optionally substituted on carbon
- 25 by one or more R^{57} ;
- p is 1;
- q is 0;
- r is 0;
- m is 0;
- 30 n is 1;
- z is 1; and
- R^{28} , R^{47} and R^{57} are independently selected from halo and hydroxy

or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

11. A compound of formula (I) wherein:

M^1 is $-\text{CH}_2-$;

5 M^2 is $-\text{CR}^{22}\text{R}^{23}-$ and $-\text{NR}^{24}-$;

R^{22} and R^{23} are independently selected from hydrogen and hydroxy;

One of R^1 and R^2 is ethyl and the other is butyl;

v is 0;

R^4 and R^7 are hydrogen;

10 One of R^5 or R^6 is selected from a group of formula (IA) (as depicted above) and the other is hydrogen or methylthio;

Z is $-\text{O}-$ or $-\text{S}(\text{O})_b-$; wherein b is 0;

R^8 is hydrogen;

R^9 is hydrogen;

15 R^{10} and R^{11} are independently selected from hydrogen, 2-fluorophenyl or carbocyclyl;

R^{13} is a group of formula (IB) (as depicted above);

R^{14} is hydrogen;

R^{15} is hydrogen;

20 R^{17} is pentyl substituted by 5 hydroxy; or R^{17} is a group of formula (IC) (as depicted above) wherein:

R^{18} is selected from hydrogen;

R^{19} is selected from hydrogen;

R^{20} is pentyl substituted by 5 hydroxy;

p is 1;

25 q is 0;

r is 0;

m is 0;

n is 1; and

z is 1;

30 or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

12. A compound of formula (I) selected from:

(+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl}carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;

(+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl}carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;

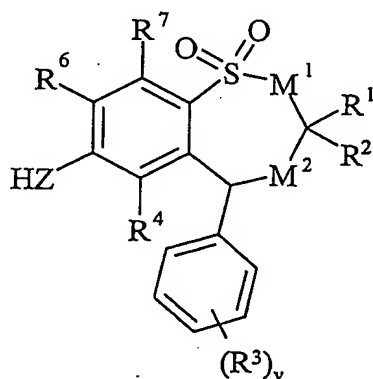
1,1-dioxo-3-ethyl-3-butyl-4-hydroxy-5-phenyl-7-(N-{ α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-2-fluorobenzyl}carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine; or

10 1,1-dioxo-3-butyl-3-ethyl-4-hydroxy-5-phenyl-7-(N-{1-[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-1-(cyclohexyl)methyl}carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine;

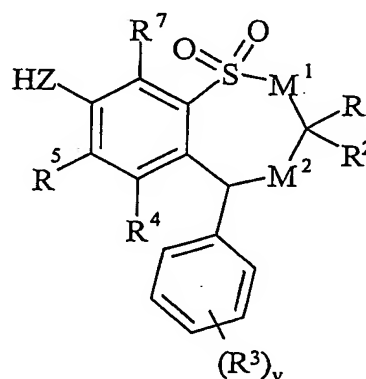
or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

15 13. A process for preparing a compound of formula (I) or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in anyone of claims 1-12, which process (wherein variable groups are, unless otherwise specified, as defined in claim 1) comprises of:

Process 1): for compounds of formula (I) wherein Z is -O-, -NR^a or -S-; reacting a compound
20 of formula (IIa) or (IIb):

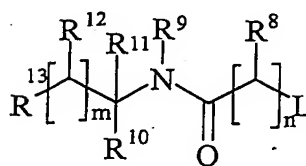


(IIa)



(IIb)

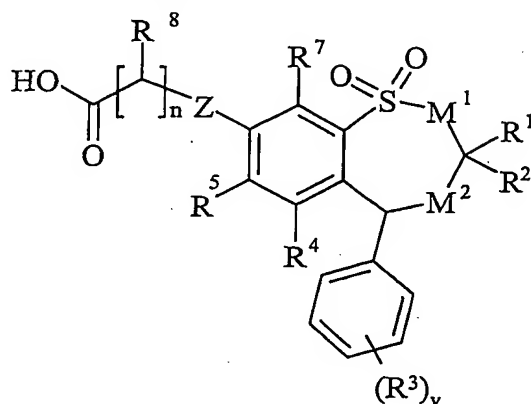
with a compound of formula (III):



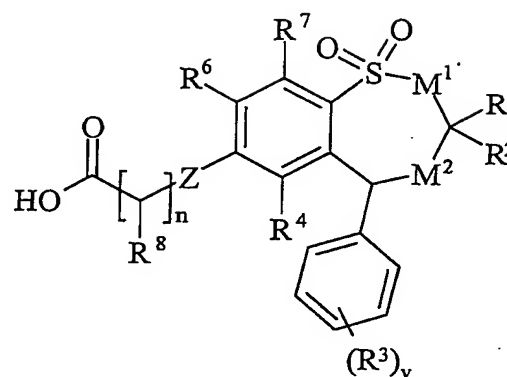
(III)

wherein L is a displaceable group;

Process 2): reacting an acid of formula (IVa) or (IVb):

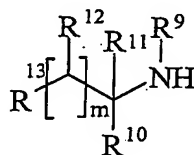


(IVa)



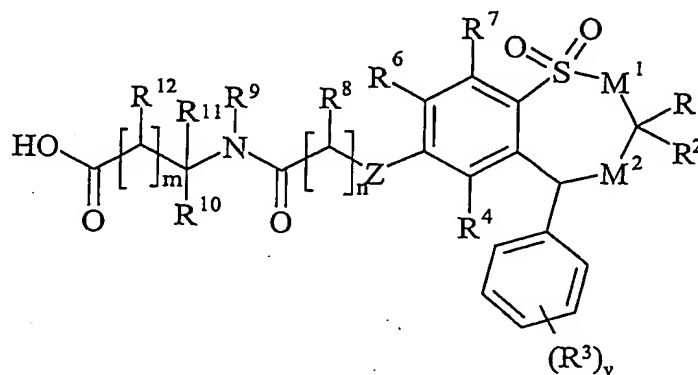
(IVb)

or an activated derivative thereof; with an amine of formula (V):



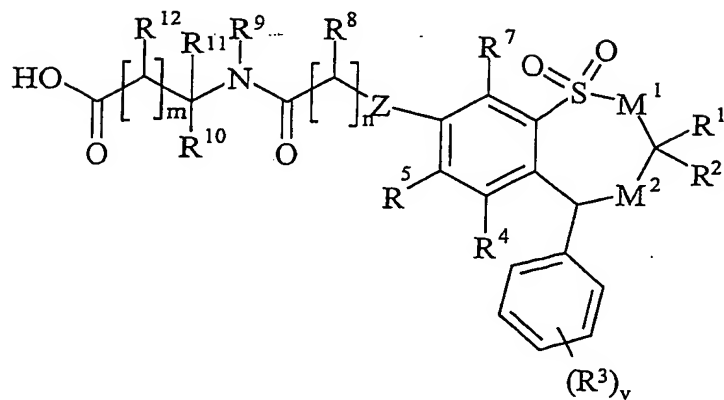
(V);

10 Process 3): for compounds of formula (I) wherein R¹³ is a group of formula (IB); reacting an acid of formula (VIa):



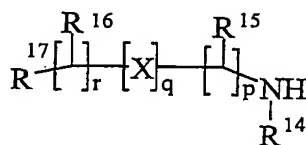
(VIa)

or (VIb):



(VIb)

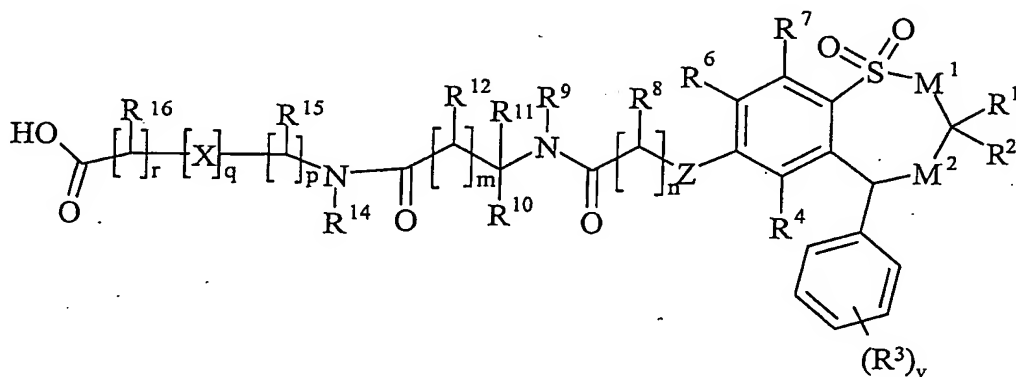
with an amine of formula:



5

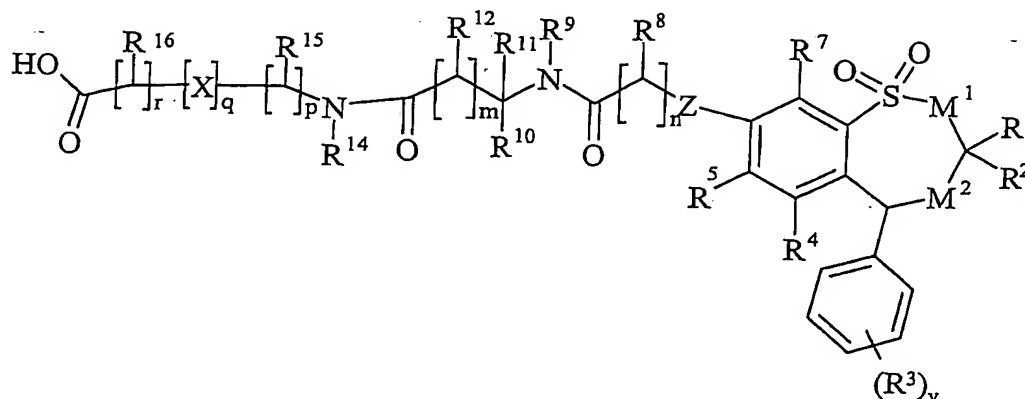
(VI)

Process 4): for compounds of formula (I) wherein R¹³ is a group of formula (IB) and R¹⁷ is a group of formula (IC); reacting an acid of formula (VIIIa):



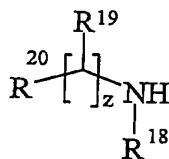
(VIIIa)

10 or (VIIIb)



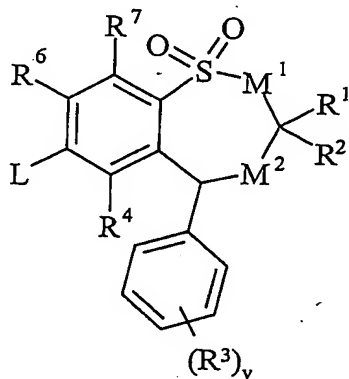
(VIIIb)

or an activated derivative thereof; with an amine of formula (IX):

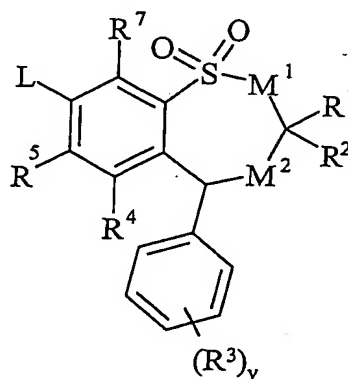


(IX)

Process 5) for compounds of formula (I) wherein one of R⁵ and R⁶ are independently selected from C₁₋₆alkylthio optionally substituted on carbon by one or more R²⁵; reacting a compound of formula (Xa) or (Xb):



(Xa)



(Xb)

wherein L is a displaceable group; with a thiol of formula (XI):



(XI)

wherein R^m is C₁₋₆alkylthio optionally substituted on carbon by one or more R²⁵;

and thereafter if necessary or desirable:

i) converting a compound of the formula (I) into another compound of the formula (I);

- ii) removing any protecting groups;
- iii) forming a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug.

14. A compound of the formula (I), or a pharmaceutically acceptable salt, solvate, solvate
5 of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 for use as a
medicament.

15. A compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of
such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 for use in a method of
10 prophylactic or therapeutic treatment of a warm-blooded animal, such as man.

16. The use of a compound of the formula (I), or a pharmaceutically acceptable salt,
solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 in
the manufacture of a medicament for use in the production of an IBAT inhibitory effect in a
15 warm-blooded animal, such as man.

17. A method for producing an IBAT inhibitory effect in a warm-blooded animal, such as
man, in need of such treatment which comprises administering to said animal an effective
amount of a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate
20 of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12.

18. A pharmaceutical composition which comprises a compound of formula (I), or a
pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as
claimed in any one of claims 1 to 12, in association with a pharmaceutically-acceptable
25 diluent or carrier.

19. A combination comprising a compound of formula (I), or a pharmaceutically
acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of
claims 1 to 12, and an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt,
30 solvate, solvate of such a salt or a prodrug thereof.

20. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and a bile acid binder.

5 21. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, and a bile acid binder.

10 22. A combination according to claim 19 or claim 21 wherein the HMG Co-A reductase inhibitor is atorvastatin, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

23. A combination according to claim 19 or claim 21 wherein the HMG Co-A reductase
15 inhibitor is rosuvastatin, or a pharmaceutically acceptable salt thereof.

24. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 and a PPAR alpha and/or gamma agonist, or a pharmaceutically acceptable salt
20 thereof.

25. A composition according to claim 24 wherein the PPAR alpha and/or gamma agonist is (S)-2-ethoxy-3-[4-(2-{4-methanesulphonyloxyphenyl}ethoxy)phenyl]propanoic acid or a pharmaceutically acceptable salt thereof.

25